JUN 23 2006

510(k) Premarket Notification K060900

Spacelabs Medical

Bispectral Index (BISx) Analysis Module 91482 and Accessories

Summary of Safety and Effectiveness

May 15, 2006

The 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 1992.

Subject:	510(k) Summary of Safety and Effectiveness Information for the Spacelabs Medical Bispectral Index (BISx) Analysis Module 91482
Submitter:	Spacelabs Medical, Inc. PO Box 7018 Issaquah, WA 98029 David J. Geraghty Phone: 1 425 657 7200 Fax: 1 425 657 7207 david.geraghty@slmd.com
Proprietary Name:	Spacelabs Medical Bispectral Index (BISx) Analysis Module, model 91482
Common Name and Classification:	Electroencephalograph (EEG) Monitor (84 GWQ, §882.1400, Class II)
Device Description:	The Spacelabs Medical Bispectral Index (BISx) Analysis Module 91482 (BISx Module 91482) is an easy-to-use, slim, single module in the Spacelabs Medical family of Spacelabs Medical Ultraview System (Ultraview) modules. The BISx Module 91482 is a microprocessor based, two-channel EEG unit designed for use on adult and pediatric patients within a hospital or medical facility. Its system configuration includes the BISx Module 91482 with connectors for external serial data connections, a BISx pod, a patient interface cable, disposable sensors, and printer options. The BISx pod, patient interface cable and disposable sensors are manufactured by Aspect Medical Systems, and distributed by Spacelabs Medical for use with the BISx Module 91482. The Spacelabs Medical Ultraview monitor provides the display capabilities for the care provider.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Spacelabs Medical Inc.
c/o Mr. David J. Geraghty
Manager, Regulatory and Quality
P.O. Box 7018
Issaquah, Washington 98027

APR - 9 2012

Re: K060900
Trade/Device Name: Spacelabs Medical Bispectral Index (BIS) Analysis Module 91482 and Accessories
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLW, OMC, OLT, ORT
Dated (Date on orig SE ltr): May 23, 2006
Received (Date on orig SE ltr): May 25, 2006

Dear Mr. Geraghty:

This letter corrects our substantially equivalent letter of June 23, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Kesia Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060900

Device Name: Spacelabs Medical Bispectral Index (BIS) Analysis Module 91482, and Accessories

Indications for Use:

The Spacelabs Medical Bispectral Index (BISx) Analysis Module 91482 is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. It is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals.

The Spacelabs Medical Bispectral Index (BISx) Analysis Module 91482 may be used as an aid in monitoring the effects of certain anesthetic agents. Use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060900